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10/510,492	05/23/2005	Andreas Menne		1537

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EXAMINER

ABRAHAM, SALTU M

ART UNIT

PAPER NUMBER

3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,492

Applicant(s)

MENNE ET AL.

Examiner

SALIEU M. ABRAHAM

Art Unit

3768

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments/Remarks

1. Examiner acknowledges amendments to claims 1 and 2, cancellation of claims 10 and 11 and the addition of new claims 13-16. Claims 1-9 and 12-16 are pending in the application.
2. Applicant's arguments with regard to claims 1-16 filed April 1, 2008 have been fully considered, but are moot in light of new grounds of rejection necessitated by amendments to the claims.
3. As a result of the items supra, the instant Office Action is now made final.

Claim Objections

4. Claim 14 is objected to because of the following informalities: the word "entirely" should be replaced with "entirety".
Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claims 1-9 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,727,875 to Dory (Dory) in view of US Pat. No. 5,160,336 to Favre (Favre).

In Reference to Claims 1-12

Dory teaches:

A medical instrument for the treatment of biological tissue, comprising:

a) a means for generating extracorporeal pressure waves, (see abstract, and figure 1)

and

b) a transmission element (2) for coupling the pressure waves into the body of living beings, (see figure 1, reference mark 103)

c) pressure wave coupling to the "transmission element by an impact member (10) hitting a transmission element (2) and the pressure wave propagates in the transmission element (2)" (**see figure 1, reference marks 1-2, 103 and L**)

However, Dory fails to teach an inwardly curved exit boundary surface for pressure wave coupling into the biological tissue or a horn-shaped transmission element having larger diameter at the exit boundary surface than at an axially opposite entry boundary surface.

In the same field of endeavor, Favre teaches the use of a projectile or ballistic-type shock wave generator for medical purposes that is "of simple and inexpensive construction" (**see column 2, lines 5-10 and lines 29-47**). Favre further teaches the use of a horn-shaped transmission element to facilitate wave propagation and focusing on the target site (see columns 1, lines 57-61).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the transmission apparatus of Favre including the horn-shaped element in the medical instrument of Dory in order to facilitate pressure wave propagation as taught by Favre.

In Reference to Claim 2

Dory in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as defined in claim 1, characterized in that wherein the means for generating the pressure

waves is an impact member (10) guided in a housing and adapted to reciprocated by

means of a drive means,

the impact member (10) exerting one or more impulses on the transmission element (2) and inducing a pressure wave

in the transmission element (2) due to the impulse, said pressure wave propagating to the exit boundary surface (19) of the transmission element (2). **(see abstract and column 2, lines 29-47).**

In Reference to Claim 3

Dory in view of Favre has been shown to teach all of the limitations of claim 2. Favre further discloses:

The medical instrument as defined in claim 2, characterized wherein the impact member (10) is arranged coaxially to the transmission element (2) (see figure 1, reference marks 6 and 12).

In Reference to Claim 4

Dory in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument defined in claim 1, wherein the pressure wave source may be driven periodically, the impact member (10) and the transmission

element (2) being self-returnable. (see figure 1, reference marks 6, 10 and 12) and column 2, lines 35-54).

In Reference to Claim 5

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as defined in claim 1, wherein the impact frequency of the impact member (10) is about 1 to 30 Hz, preferably 1 to 12 Hz. (see column 2, lines 54-55).

In Reference to Claim 6

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as defined in claim 1, wherein a spring/damping element (15) is provided between the transmission element (2) and the housing (4). (see figure 1, reference marks 10, 6 and 9, and 12).

In Reference to Claim 7

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as defined in claim 1, wherein the exit boundary surface (19) of the transmission element (2) travels a stroke of less than 0.5 mm due to the impulse. (see column 3, lines 10-47)

In Reference to Claim 8

Dory in view of Favre has been shown to teach all of the limitations of claim 1. Dory further teaches:

The medical instrument as defined in claim 1, wherein an intermediate element (9) is arranged between the impact member (10) and the transmission element (2), which intermediate element passes the impulse from the impact member (10) to the transmission element (2) (**see figures 1, reference marks 1-2 and 103**).

In Reference to Claim 9

Dory in view of Favre has been shown to teach all of the limitations of claim 1. Dory further teaches:

The medical instrument as defined in claim 1, wherein the outer edges of the exit boundary surface of the transmission element are rounded or provided with a protective coating (**see figures 1, reference mark 103**).

In Reference to Claim 12

Dory in view of Favre has been shown to teach all of the limitations of claim 1. Dory further discloses:

The medical instrument as defined in claim 1, wherein the impedance-adjusting media (5) are provided between the exit boundary surface (19) of the transmission element (2) and the biological tissue for improving the coupling of the pressure wave into the biological tissue. (**see figures 1, reference marks L and 103**).

In Reference to Claims 13-16

Dory in view of Favre have been shown to teach substantially all of the cited claim features (see rejections *supra*). In addition, Dory further teaches wherein the impact member hits an entry boundary face of a transmission element and the impedance – adjusting means is an acoustically conductive medium located next to/around the opening exit boundary surface (see Dory **figure 1, reference marks 1, 2, 103 and L**).

7. Claims 1-9 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,727,875 to Dory (Dory) in view of US Pat. No. 6,036,661 to Schwarze (Schwarze).

In Reference to Claims 1-9 and 12-16

Dory teaches substantially all features in the claims (**see claim rejections *supra*, claims 1-3 and 6-8 and figure 1**). However, Dory is silent with regard to an exponential horn-shaped transmission element.

Schwarze, in the same field of endeavor discloses a shockwave apparatus for medical applications that produces focused pressure waves for treating calculi in the body (**see abstract**). Schwarze further discloses a multiplicity of focus means (to include transmission elements/acoustic lenses) to be applied based upon the desired target location/depth and pressure profile (**see column 2, lines 29-41**). It would be obvious of one of ordinary skill to employ a horn- or any other similarly shaped or functionally equivalent transmission element in order to customize the resulting pressure wave profile and focus characteristics for a given target/anatomical site as disclosed by Schwarze.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 9:30 am - 7:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/30/08 SA

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